DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 3/18/2008.

Claims 1-13 were cancelled. Claim 14 is new.

Response to Arguments

Applicant's amendments render the art-based rejections moot. Claims 10-13 were rejected under 35 USC 102 (see Office Action dated 9/25/2007). Said claims were drawn to a method of treating/inhibiting proliferation of influenza and compositions thereof. Applicant subsequently cancelled said claims and introduced a new claim (i.e., claim 14) drawn to a method of preventing an influenza flu infection. The art of record does not apply to the new claim. Accordingly, the rejections of claims 10-13 under 35 USC 102 have been withdrawn. However, a new rejection under 35 USC 112 is made in light of applicant's amendments.

NEW REJECTIONS

The following rejections are new in light of applicant's amendment submitted 3/18/2008:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to a method of preventing influenza. The relative skill of those in the art is high, generally that of an M.D. or Ph.D. That factor is outweighed, however, by the predictable nature of the art. As illustrative of the state of the art, the examiner cites Yang et al., Harper et al., and Mitra et al.

Yang et al. teaches that ambroxol suppresses influenza-virus proliferation in a mouse by increasing antiviral factor levels (abstract).

Harper et al. teaches vaccinations are the most effective means for reducing the effect of influenza (page 7). Harper et al. also teaches that the effectiveness of the inactivated influenza vaccine depends primarily on the age and immunocompetence of the vaccine recipient and the degree of similarity between the viruses in the vaccine and those in circulation (page 10). Additionally, Harper discloses percentages for different

patient populations as to how effective the inactive and active forms the vaccine perform (pages 10-13).

Mitra et al. teaches compositions and methods for providing improved treatment, management or mitigation of cold, cold-like and/or flu symptoms by administering a safe and effective amount of a composition comprising an amino acid salts of propionic acid nonsteroidal anti-inflammatory agent along with at least one of (a) a decongestant, (b) an expectorant, (c) an antihistamine and (d) an antitussive (see Abstract and claim 1). Mitra also names the specific expectorants, "bromhexine and ambroxol, mixtures thereof or pharmaceutically acceptable salts thereof' (see claim 3).

That references plainly demonstrate that preventing influenza is an art recognized hurdle. The references also demonstrate that influenza can be treated, proliferation can be suppressed, and the incidence thereof can be reduced, however there is nothing in the art that supports prevention of infection of the flu virus.

2. The breadth of the claims

The claim is broad, reciting a method for prevention of an influenza virus infection in a warm-blooded animal comprising administering to said animal a therapeutically effective amount of a composition comprising an agent selected from ambroxol, bromhexine, pharmaceutically acceptable salts thereof and combinations thereof, and an additive.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for determining the particular administration regimes (dosages, timing, administration routes, etc.) necessary to prevent an influenza virus infection in all warm-blooded animals. The working examples are limited to treating and inhibiting proliferation of the influenza virus. Thus, the applicant at best has provided specific direction or guidance only for treating and inhibiting proliferation of an influenza virus infection. No reasonably specific guidance is provided concerning useful preventive protocols for an influenza virus infection.

4. The quantity of experimentation necessary

Because of the known art-recognized hurdle (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that the instantly claimed method could be predictably used to prevent an influenza virus infection as inferred in the claims and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nilsen et al. (5,885,594) teaches well-known orally administrable compositions for treating flu symptoms comprising expectorants such as ambroxol and pharmaceutically acceptable salts thereof (see col. 9, line 49 - col. 10, line 14).

Conclusion

All claims have been rejected; no claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615